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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/039,260	03/16/1998	A.K. GUNNAR ABERG	4821-306	9369

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PENNIE & EDMONDS
1155 AVENUE OF THE AMERICAS
NEW YORK, NY 100362711

EXAMINER	
CRANE, LAWRENCE E	
ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 10/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/039,260	ABERG ET AL.	
	Examiner	Art Unit	
	L. E. Crane	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 August 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *48,52,54,61 and 69-71* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *48,52,54,61 and 69-71* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *06/15/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims **1-47, 49-51, 53, 55-60 and 62-68** have been cancelled, claims **48, 54 and 61** have been amended, and new claims **69-71** have been added as per the amendment of August 12, 2005. Receipt of the Statement filed under 37 C.F.R. §3.73(b) is noted. No additional Information Disclosure Statements (IDSs) have been filed as of the date of completion of this Office Action.

Claims **48, 52, 54, 61 and 69-71** remain in the case.

Claim **48** is rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim **48** the term "for the treatment of allergic rhinitis or urticaria" fails to further limit the scope of a pharmaceutical compositions claim and is therefore irrelevant. The patentable weight of a pharmaceutical composition claim is limited to the identity or identities of the active ingredient or ingredients, the quantity or dosage of the active ingredient per unit of the composition, the identity of the carrier or carriers and their physical form, and the relative proportions of the carrier(s) to the active ingredient(s). The noted term is a method of treatment claim limitation only. Deletion of the noted term is therefore respectfully requested.

Applicant's arguments with respect to claim **48** have been considered but are deemed to be moot in view of the new grounds of rejection necessitated by applicant's amendment of claim **48**.

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel,* 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam,* 686 F. 2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi,* 759 F.2d 887, 225 USPQ 645 (Fed. Cir 1985); and *In re Goodman,* 29 USPQ 2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double

patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. §1.78(d).

Effective January 1, 1994, a registered attorney or agent or record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. §3.73(b).

Claims **48, 52, 69 and 70**, and claim **71** to the degree to which it applies, are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***48-57*** of copending Application No. **10/989,514**. Although the conflicting claims are not identical, they are not patentably distinct from each other because the pharmaceutical composition claims and the active ingredients defined therein are directed to substantially overlapping subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments with respect to claims **48 and 52** have been considered but are deemed to be moot in view of the new ground of rejection, which ground has been necessitated by applicant's filing of an additional related patent application.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

"A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent."

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States."

Claims **48, 52, 69 and 70**, and claim **71** to the degree to which it applies, are rejected under 35 U.S.C. §102(**b**) as being anticipated by **Villani et al. '716** (PTO-1449 ref. **AC**).

Applicant is referred to the Villani et al. reference at column 8, lines 32-44, wherein the incorporation of descarbethoxyloratadine (DCL) as the active ingredient in a pharmaceutical preparation (aka a "pharmaceutical composition") is disclosed along with a range of unit

dosages between 1mg and 1000 mg. Applicant is also referred to column 24, lines 44-54 wherein administration of DCL via a pharmaceutical composition to a human host is specifically taught.

Applicant's arguments with respect to claims **48 and 52** have been considered but are deemed to be moot in view of the new grounds of rejection necessitated by applicant's amendment of claim **48**. The rejection has been made without consideration of the substance of the amendment to claim **48** at lines 1-2 because said amendment is deemed to have failed to add a patentable distinction as noted in the rejection under 35 U.S.C. §112, second paragraph, supra.

The following is a quotation of 35 U.S.C. §103(**a**) which forms the basis for all obviousness rejections set forth in this Office action:

> "A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made."

Claims **54 and 61** and claim **71** to the degree to which it applies, are rejected under 35 U.S.C. §103(a) as being unpatentable over **Villani et al. '716** (PTO-1449 ref. **AC**) in view of **Berkow et al.** (PTO-892 ref. **R**).

The instant claims are directed to a pharmaceutical composition wherein the antihistamine DCL and the decongestant pseudoephedrine are the active ingredients. The instant claims are also directed to pharmaceutical compositions comprising DCL and pseudoephedrine with a range of dosages of DCL, to a more narrowly defined dose of DCL, and to modes of administration by oral delivery of a tablet or a capsule.

Villani et al. '716 discloses at column 8, lines 42-46, the combination of DCL and a decongestant in a single pharmaceutical composition. This reference also discloses at column 1, lines 39-46, and in claims ***11-16***, that administration of DCL is effective in the treatment of " ... allergic reactions in a mammal." This reference discloses the oral, parenteral, rectal, and transdermal routes of administration of the noted composition. This reference does not disclose pharmaceutical compositions wherein a specific decongestant or decongestants has or have been specified.

Berkow et al. discloses at p. 326 following the heading "Allergic Rhinitis" and under the sub-heading "Treatment" at lines 1-6, in particular lines 4-6, the combination of an antihistamine with the decongestant "pseudoephedrine" in a single pharmaceutical composition. This reference does not disclose pharmaceutical compositions wherein DCL has been specified as the active antihistamine.

The noted teaching of the Villani reference clearly motivates the ordinary practitioner to go out and find a decongestant to combine with DCL in a binary pharmaceutical composition. Similarly, in its discussion of the treatment of allergic rhinitis and related conditions in humans, the Berkow reference motivates one of ordinary skill to seek out an antihistamine to combine with pseudoephedrine to make effective pharmaceutical compositions. For these reasons the instant claims are deemed to lack patentable distinction in view of the noted prior art references which both provide motivation to produce the specific combination of active ingredients specified in claim **54**.

Therefore, the instant claimed binary pharmaceutical compositions comprising DCL and a decongestant, pseudoephedrine in particular, would have been obvious to one of ordinary skill in the art having the above cited references before him at the time the invention was made.

Applicant's arguments with respect to claims **54 and 61** have been considered but are deemed to be moot in view of the new ground of rejection, wherein said ground has been necessitated by applicant's amendment of claims **54 and 61**.

Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. §1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. §1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. §103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. §1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. §103(c) and potential 35 U.S.C. §§102(f) or (g) prior art under 35 U.S.C. §103(a).

Papers related to this application may be submitted to Group 1600 via facsimile transmission (FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone number to FAX (unofficially) directly to Examiner's computer is 571-273-0651. The telephone number for sending an Official FAX to the PTO is 703-872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **571-272-0651**. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson, can be reached at **571-272-0661**.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is **571-272-1600**.

LECrane:lec
10/20/2005

L. E. Crane, Ph.D., Esq.
Primary Patent Examiner
Technology Center 1600